



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,452	06/10/2005	Judith McNally	06275-455US1 100927-1P US	3793
26164 7590 10/27/2008 FISH & RICHARDSON P.C. P.O BOX 1022 MINNEAPOLIS, MN 55440-1022				
EXAMINER ANDERSON, REBECCA L				
ART UNIT		PAPER NUMBER		
1626				
NOTIFICATION DATE		DELIVERY MODE		
10/27/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary

Application No.

10/538,452

Applicant(s)

MCINALLY ET AL.

Examiner

REBECCA L. ANDERSON

Art Unit

1626

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9, 11, 12 and 14-20 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-6, 9 and 18-20 is/are rejected.
- 7) ☒ Claim(s) 2, 7, 12 and 15-17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-7, 9, 11, 12 and 14-20 are currently pending in the instant application. Claims 1,3-6, 9 and 18-20 are rejected. Claims 2, 7, 12 and 15-16 are objected. Claims 11 and 14 are withdrawn from consideration as being for non-elected subject matter.

Response to Amendment and Arguments

Applicants' amendment and arguments filed 11 July 2008 have been fully considered. Applicants' amendment has overcome the 35 USC 112 1st paragraph rejection of claims 10 and 13 as these claims have been cancelled. Therefore, the search and examination has been expanded, according to MPEP 803.02, and now includes the entire subject matter of the pending claims. Therefore, the objection to claims 1, 3, 7-9, 10, 12, 13 and 18-20 as containing non-elected subject matter is withdrawn. The additional search and examination of the subject matter claimed, based upon applicants' amendment to overcome the 35 USC 112 1st paragraph rejection, has resulted in the following objection and rejection of the pending claims.

Claim Objections

Claims 2, 7, 12 and 15-17 are objected to as being dependent upon a rejected base claim, but would appear allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-6, 9 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/069901 (PRASIT).

Determining the scope and contents of the prior art

PRASIT discloses the compounds of the formula I, page 4 wherein R5 is as found on page 5, lines 33-35 and page 6, lines 1-11 and n is one or two (page 6, line 27). E, D, X, R4, R3, R2, R1 are defined in the preferred embodiments to include E as piperazinyl, page 7, line 30; D as pyridinyl, page 7, line 20; X as NH, page 7, line 11; R4

as H, page 8, line 12 and 13; R3 as C1-6 alkyl such as isobutyl, page 8, line 12 and 13; R2 as hydrogen, page 8, line 5; R1 as hydrogen, page 8, line 5. Pharmaceutical compositions are disclosed on page 29.

Ascertaining the differences between the prior art and the claims at issue

The difference between the prior art and the subject matter of the claims at issue is that the prior art does not specifically disclose a specific compound of the instantly claimed formula (I). However, the prior art discloses the compounds of the formula I, which generically overlap with applicants' instantly claimed products. Furthermore, the prior art does disclose preferences towards applicants' instantly claimed products which provides direction and motivation to prepare the subject matter of applicants' instantly claimed invention.

Resolving the level of ordinary skill in the pertinent art

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the compounds within applicants instant compound of formula (I) when faced with the prior art of PRASIT since the prior art discloses products and pharmaceutical compositions which generically overlap with the subject matter of the claimed invention and provides direction towards applicants' subject matter of the instant claims within the preferred embodiments. The motivation would be to the expectation of preparing more biologically active compounds useful for the treatment of osteoporosis.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday from 6:00am until 2:30pm.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Rebecca Anderson/
Primary Examiner, AU 1626*

21 October 2008

Rebecca Anderson
Primary Examiner
Art Unit 1626, Group 1620
Technology Center 1600